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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/757,704	01/11/2001	Ramaz Katsarava	031848.0003	7816

26118 7590 01/27/2003

BROBECK, PHLEGER & HARRISON, LLP
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WASHINGTON, DC 20005

EXAMINER

GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 01/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/757,704

Applicant(s)

KATSARAVA ET AL.

Examiner

Isis Ghali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 and 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' declaration, request for extension of time, CFR, and preliminary amendment, all filed 09/07/2001; IDS, filed 06/21/2001; and supplemental IDC, filed 10/23/2001.

Specification

1. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 6, 7, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Saotome et al.

Saotome et al. disclosed polymers that are degraded and solubilized by the action of specific enzymes as chymotrypsin. The polymers are alpha amino acids (PEA) having the general formula as that disclosed by applicants. Leucine and phenylalanine

were used as starting esterification. The biodegradable polymer used in medical field such as controlled drug delivery. See pages 21-23 of the document. . Deformability and conformability to surface of application are inherent for the particular PEA. The limitations of claims 1-3, 6, 7, 18 are met by the reference.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 4, 5, 8-17, 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saotome et al. in view of Katsarava et al.

Saotome et al. disclosed a polymer that is degraded and solubilized by the action of specific enzymes as chymotrypsin. The polymers are alpha amino acids (PEA)

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having the general formula as that disclosed by applicants. Leucine and phenylalanine were used as starting esterification. The biodegradable polymer used in medical field such as controlled drug delivery. See pages 21-23 of the document. Deformability and conformability to surface of application are inherent for the particular PEA.

Saomote et al. do not teach the ratio of Phe-PEA to Leu-PEA (claims 4, 5), the particular bioactive agents (claims 8 and 19), the chymotrypsin enzyme adsorbed to the surface of the polymer (claims 9-12, 20-23), and the method of treating the wound (claims 13-17).

It is within the skill in the art to select optimal parameters such as ratios and weight percents of components in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980). Therefore, the ratio of Phe-PEA to Leu-PEA instantly claimed in claims 5 and 6 are not considered critical absent evidence showing unexpected and superior results.

Katsarava et al. teach film wound dressing that used to accelerate wound healing (the method of claims 13-17), comprising antiseptic and biodegradable material based on poly (esteramide) (PEA) with prolonged action. The polymer is impregnated with bio-bacteriophages and proteolytic enzyme alpha chymotrypsin immobilized at the surface (claims 8-12, 19-23). See the entire document.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver a wound dressing made of PEA as disclosed by Saomote et al. as a suitable material for drug delivery, and add the bacteriophages and the chymotrypsin enzyme to the polymer to provide a wound dressing, motivated by the

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teaching of Katsarava that the wound dressing comprising the PEA, bacteriophage and chymotrypsin achieve the elimination of toxic component, the attachment of the biodegradation properties and the simplification of the preparation processing, with reasonable expectation of success of the delivered dressing in treating different kinds of wounds and ulcers.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali
Examiner
Art Unit 1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600